

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent of:

Konstantin Konstantinov et al.

Application No.: 10/532,998

Confirmation No.: 1655

Patent No.: 7,674,885

Issue Date: March 9, 2010

Art Unit: 1656

For: PROCESS FOR CONCENTRATION OF  
MACROMOLECULES

Examiner: Suzanne Marie Noakes

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**  
**UNDER 37 C.F.R. § 1.705(d)**

MS Petition  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The above patent issued on March 9, 2010 indicating on the face that it was entitled to a 618 day Patent Term Adjustment. Applicants respectfully request reconsideration of the Patent Term Adjustment under 35 U.S.C. 154(b). In particular, Applicants request that the Patent Term Adjustment be reconsidered (1) based on the date that the national stage commenced under 35 U.S.C. § 371(b) or (f) and (2) based on the actual completion date of the requirements under 35 U.S.C. § 371.

The USPTO implemented the three-year pendency provision in 35 U.S.C. § 154(b)(1)(B) which provides that an applicant is entitled to additional patent term adjustment if the issue of an original patent is delayed due to the failure of the USPTO to issue a patent within three years after the actual filing date of the application. Pursuant to the Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.S.C. § 371 ("Notice") dated September 10, 2009 (1347 OG 49), the three-year pendency provision in 35 U.S.C. § 154(b)(1)(B) should be

measured from the date that the national stage commences under 35 U.S.C. § 371 (b) or (f) in an international application.

The present application is a national stage application of the international application no. PCT/US03/34522 pursuant to 35 U.S.C. § 371, with the national stage commencing at the latest on May 1, 2005 under 35 U.S.C. § 371 (b). The application was accorded the date of November 10, 2005 as the date of completion of all 35 U.S.C. § 371 requirements (i.e. 371(c) date). However, this was not the correct 371 (c) date. As shown in the attached postcard stamped by the OIPE, the declaration was received in the USPTO on October 11, 2005, not November 10, 2005. Also attached is a copy of the Response to the Notice of Missing Requirements, which also evidences this date of submission of the declaration through a certificate of mailing and other dated documents. The USPTO transposed the numbers for 10/11/05 to 11/10/05. This error led to USPTO errors in determining the Patent Term Adjustment.

For purposes of calculating B delay, the date the national stage was commenced should be used as the starting date for determining whether more than three years were required to issue a patent, and that national stage commencement date was May 1, 2005. Pursuant to the above-referenced Notice, Applicants respectfully request reconsideration of the Patent Term Adjustment based at the latest on the date of May 1, 2005 under 35 U.S.C. § 371 (b) or (f).

The correct Patent Term Adjustment is believed to be calculated as follows. The period of A delay was 393 days. The requirements under 35 U.S.C. § 371 were fulfilled with the filing of the declaration on October 11, 2005. Fourteen months after this date was December 11, 2006. An Office Action did not issue until January 9, 2008. The period of A delay began December 12, 2006 and ended January 9, 2008, which totaled 393 days. The period of B delay is calculated starting with the date that the national stage commenced under 35 U.S.C. § 371, which was May 1, 2005. The B delay began three years later, on May 1, 2008. The patent issued on March 9, 2010. The B delay is the days between May 1, 2008 and March 9, 2010, which is 677 days.

Applicants calculate 225 days of Applicant delay.

There is no overlap between the A and B delays because the A delay occurred between December 12, 2006 to January 9, 2008 and the B delay occurred from May 1, 2008 to March 9, 2010. There is no overlapping day.

The Patent Term Adjustment is A delay (393 days) plus B delay (677 days) minus Applicant's delay (225), which equals 845 days.

Accordingly, the Patent Office assessment of 618 days is in error and correction to 845 days is required.

Alternatively, Applicants note that the USPTO has interpreted 35 U.S.C. § 154 (b) (1) (B) such that any time between filing a notice of appeal and mailing of a notice of allowance is subtracted from the time of B delay. 37 C.F.R. § 1.703 (b) (4). Applicants respectfully disagree with this interpretation. The clear language of 35 U.S.C. § 154 (b) provides that if a delay requested by the Applicant – such as appellate review – is resolved such that the patent is issued reversing an adverse determination of patentability, the term of the patent shall be extended 1 day for each day or the pendency of the proceeding. Assuming that merely filing a notice of appeal without a brief is appellate review and therefore “a delay...requested by the applicant” under section 154(b)(1)(B), then the favorable result of a Notice of Allowance issuing soon after the filing of the notice of Appeal should be considered a reversal of an adverse determination of patentability. Accordingly, the time between the filing of the notice and the mailing of the Notice of Allowance should be counted toward the B delay and not subtracted from it, as the USPTO asserts in rule 703(b)(4).

Nevertheless, if the USPTO were to follow Rule 703(b) (4), then it seems that an additional five days would be subtracted from the B delay, for a total B delay of 672 days. This is because a Notice of Appeal was filed on December 10, 2009, and a Notice of Allowance was mailed on December 15, 2009. In the alternative, if the USPTO does not grant a Patent Term Adjustment of 845 days, then an Adjustment of 840 days is requested.

Accompanying with this request is the petition fee in the amount of \$200.00 pursuant to 37 C.F.R. § 1.18(e). No further fee is believed due. However, if a fee is due, please charge our

Patent No.: 7,674,885  
Request for Reconsideration of Patent Term Adjustment  
Dated April 6, 2010

Docket No.: BABIO-MSB-8012 US

Deposit Account No. 03-2775, under Order No. 07430-00191 from which the undersigned is authorized to draw.

Applicants further request that a Certificate of Correction pursuant to 37 CFR §1.322 be provided by the Commissioner if the patent term adjustment is ultimately granted after issuance of the patent.

Dated: April 6, 2010

Respectfully submitted,

Electronic signature: /Christine M. Hansen/  
Christine M. Hansen

#758790

Registration No.: 40,634  
CONNOLLY BOVE LODGE & HUTZ LLP  
1007 North Orange Street  
P. O. Box 2207  
Wilmington, Delaware 19899-2207  
(302) 658-9141  
Attorney for Applicant

7430 \*191 USU  
Serial/Intf. No.: 10/532,998 Docket No.: MSB-8012 Atty: CMH  
Names: Konstantin Konstantinov et al.  
Title: Process for Concentration of Macromolecules  
The following, due 11/16/05 in the U.S. Patent Office, has been  
received there on the date stamped hereon.

- ☒ Declaration or ☐ Oath } *Combined*  
☒ Power of Attorney }  
☐ Specification ☐ Claims  
☐ Preliminary Amendment  
☐ Assignment/Cover Sheet  
☐ Drawing(s) \_\_\_\_\_ sheet(s)  
☐ Priority Document(s)  
☐ Disclosure Statement (Rule 56.02)  
☐ PTO 1449 w/reference(s)  
☒ PTO 1533 Submission of Missing Parts

- ☐ Check(s) \_\_\_\_\_  
☐ Amendment or Response  
☐ Declaration or Affidavit  
☐ Notice of Appeal ☐ Brief  
☐ CPA/DIV/CIP  
☐ Extension of Time  
☐ ~~Issue~~ Fee Transmittal *for FY 2005*  
☐ Prelim. Statement ☐ Motion  
☐ Letter

☒ *copy of Notice of Missing Requirements*

Docket No.: 07430-00191-USU  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Konstantin Konstantinov et al.

Conf. No.: 1655

Application No.: 10/532,998

Group Art Unit: N/A

Filed: April 28, 2005

Examiner: Not Yet Assigned

For: PROCESS FOR CONCENTRATION OF  
MACROMOLECULES

**RESPONSE TO NOTIFICATION OF  
MISSING REQUIREMENTS UNDER 35 U.S.C. 371  
IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notification of Missing Requirements under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) mailed September 16, 2005 (enclosed herewith), Applicant respectfully submits Combined Declaration and Power of Attorney.

Please charge our Deposit Account No. 03-2775 in the amount of \$130.00 covering the fee set forth in 37 CFR 1.429(h). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order

Application No.: 10/532,998

Docket No.: 07430-00191-USU

No. 07430-00150-USU. A duplicate copy of this paper is enclosed.

Dated: *October 6, 2005*

Respectfully submitted,

By *Christine M. Hansen*

Christine M. Hansen

Registration No.: 40,634

CONNOLLY BOVE LODGE & HUTZ LLP

1007 North Orange Street

P.O. Box 2207

Wilmington, Delaware 19899

(302) 658-9141

(302) 658-5614 (Fax)

Attorney for Applicant

419958\_1.DOC

Application No. (if known): 10/532,998

Attorney Docket No.: 07430-00191-USU

**Certificate of Mailing under 37 CFR 1.8**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on

October 6, 2005  
Date

Signature

Jean M. Marshall

Typed or printed name of person signing Certificate

Registration Number, if applicable

(302) 658-9141

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Combined Declaration and Power of Attorney (4 pages)  
Response to Notification of Missing Requirements under 35 U.S.C. 371 in  
the United States Designated/Elected Office (DO/EO/US) (2 pages)  
Fee Transmittal (1 page)  
Charge \$130.00 to deposit account 03-2775





## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/532,998	Konstantin Konstantinov	07430-00150-USU
INTERNATIONAL APPLICATION NO.		
PCT/US03/34522		
I.A. FILING DATE	PRIORITY DATE	
11/01/2003	11/01/2002	

23416  
 CONNOLLY BOVE LODGE & HUTZ, LLP  
 P O BOX 2207  
 WILMINGTON, DE 19899

CONFIRMATION NO. 1655

371 FORMALITIES LETTER



\*OC000000017034839\*

Date Mailed: 09/16/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 04/28/2005
- Copy of the International Search Report filed on 04/28/2005
- Copy of IPE Report filed on 04/28/2005
- Preliminary Amendments filed on 04/28/2005
- Information Disclosure Statements filed on 04/28/2005
- Copy of references cited in ISR filed on 04/28/2005
- Priority Documents filed on 04/28/2005

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Surcharge.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

DEBORAH D WILLIAMS

Telephone: (703) 308-9140 EXT 205

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/532,998	PCT/US03/34522	07430-00150-USU

FORM PCT/DO/EO/905 (371 Formalities Notice)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

PROCESS FOR CONCENTRATION OF MACROMOLECULES

the specification of which was filed on November 1, 2003 as Application No. US03/34522.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by an amendment, if any, specifically referred to herein.

I acknowledge the duty to disclose all information known to me that is material to patentability in accordance with Title 37, Code of Federal Regulations, § 1.56.

FOREIGN PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

☒ no such foreign applications have been filed

☐ such foreign application have been filed as follows:

**EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

Application Number	Country	Date of Filing	Priority Claimed Under 35 USC 119
			___ Yes No ___
			___ Yes No ___
			___ Yes No ___

**ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

Application Number	Country	Date of Filing

**CLAIM FOR BENEFIT OF EARLIER U.S. PROVISIONAL APPLICATIONS**

I hereby claim priority benefits under Title 35, United States Code §119(e), of any United States provisional patent application(s) listed below:

☐ no such U.S. provisional applications have been filed.

☒ such U.S. provisional application have been filed as follows:

Application Number	Date of Filing	Priority Claimed Under 35 USC 119
60/422999	November 1, 2002	<u>X</u> Yes No ___
		___ Yes No ___
		___ Yes No ___

**CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)**

I hereby claim the benefit under Title 35, United States Code, §120 of the United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose all information that is material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56 which became available to me between the filing date of the prior application and the national or PCT international filing date of this application:

☒ no such U.S./PCT applications have been filed.

☐ such U.S./PCT application have been filed as follows:

Application Number	Relationship	Parent Application	Date of Filing

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint:

All practitioners at Customer Number 23416

all of **Connolly Bove Lodge & Hutz LLP**, 1007 North Orange Street, P.O. Box 2207, Wilmington, Delaware 19899, jointly, and each of them severally, my attorneys at law/patent agent(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the U. S. Patent and Trademark Office connected therewith.

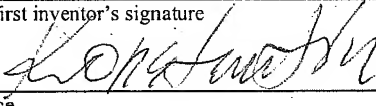
The undersigned hereby authorizes the U.S. attorney or agent named herein to accept and follow instructions from Bayer HealthCare LLC as to any action to be taken in the United States Patent and Trademark Office regarding this application without direct communication between the U.S. attorney or agent and the undersigned. In the event of a change in the persons from whom instructions may be taken, the U.S. attorney or agent named herein will be so notified by the undersigned.

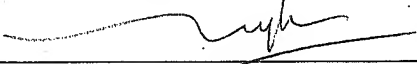
Please mail all correspondence to Christine M. Hansen, whose address is:

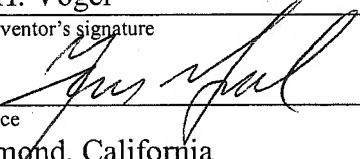
**Connolly Bove Lodge & Hutz LLP**  
1007 North Orange Street  
P.O. Box 2207  
Wilmington, Delaware 19899

Please direct telephone calls to: Christine M. Hansen at (302) 658-9141.

Please direct facsimiles to: (302) 658-5614

Full name of sole or first inventor <b>Konstantin Konstantinov</b>	
Sole or first inventor's signature 	Date <b>04/21/05</b>
Residence <b>Walnut Creek, California</b>	
Citizenship <b>US</b>	
Mailing Address  <b>116 Foxglove Lane Walnut Creek, California 94597</b>	

Full name of second inventor, if any <b>Huong Nguyen</b>	
Second inventor's signature 	Date <b>4/21/05</b>
Residence <b>San Francisco, California</b>	
Citizenship <b>US</b>	
Mailing Address  <b>751 Naples Street San Francisco, California 94112</b>	

Full name of third inventor, if any <b>Jens H. Vogel</b>	
Third inventor's signature 	Date <b>04/21/05</b>
Residence <b>Richmond, California</b>	
Citizenship <b>Germany</b>	
Mailing Address  <b>189 Shoreline Ct. Richmond, California 94804</b>	

Full name of fourth inventor, if any	
Fourth inventor's signature	Date
Residence	
Citizenship	
Mailing Address	

Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). <h2 style="text-align: center;">FEE TRANSMITTAL</h2> <h3 style="text-align: center;">For FY 2005</h3>		<b>Complete if Known</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Application Number	10/532,998-Conf. #1655
		Filing Date	April 28, 2005
		First Named Inventor	Konstantin Konstantinov
		Examiner Name	Not Yet Assigned
		Art Unit	N/A
TOTAL AMOUNT OF PAYMENT		(\$)	130.00
		Attorney Docket No.	07430-00191-USU

**METHOD OF PAYMENT** (check all that apply)

☐ Check    ☐ Credit Card    ☐ Money Order    ☐ None    ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account    Deposit Account Number: 03-2775    Deposit Account Name: Connolly Bove Lodge & Hutz LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below    ☐ Charge fee(s) indicated below, except for the filing fee  
☐ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17    ☒ Credit any overpayments

**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

<u>Total Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	<u>Multiple Dependent Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
_____	- = _____	x _____	= _____	_____	_____	_____
<u>Indep. Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>			
_____	- = _____	x _____	= _____			

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____	- 100 = _____	/50 _____ (round up to a whole number) x _____	= _____	

**4. OTHER FEE(S)**

	Fees Paid (\$)
Non-English Specification, \$130 fee (no small entity discount)	
Other (e.g., late filing surcharge): <u>1617 Surcharge-Late oath or declaration</u>	<u>130.00</u>

**SUBMITTED BY**

Signature	<u>Christine M. Hansen</u>	Registration No. (Attorney/Agent)	<u>40,634</u>	Telephone	<u>(302) 658-9141</u>
Name (Print/Type)	<u>Christine M. Hansen</u>	Date	<u>October 6, 2005</u>		